

#### REMARKS

Claims 1-9 and 11-18 stand rejected. By this paper, Applicant has amended Claims 1, 5, 11, 16-18, and 20. Applicant has canceled Claim 2 and added new Claims 21-35 which are supported at least by the originally filed claim set and page 8, lines 12-15 and 30-33 of the originally filed specification. No new matter has been added. Thus, Claims 1-3, 5-9, and 11-35 are presented for reconsideration and further examination.

#### Rejection under 35 U.S.C. §112, ¶ 2

The Examiner rejected Claims 1-4 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated that “[i]t is not clear whether applicant’s shaft has a core shaft or does not have a core shaft.”

Applicant has amended Claim 1 and canceled Claim 2. Applicant respectfully submits that these amendments overcome the rejection. The Examiner further stated that “it is not clear how something can be made from a single piece of homogenous material and has a core region.” Applicant hereby presents remarks intended to facilitate understanding of the differences between a “core shaft” and a “continuous core region.”

A “shaft comprising a single piece of homogenous material” as recited in Claim 1 does not have a core **shaft**. However, such a shaft can have a continuous core **region** as described in the specification.

The terms “core shaft” and “continuous core region” are described in the specification as two distinct concepts. In particular, page 8, lines 17-21 explain that, in one embodiment, “there is, therefore, no continuous core shaft provided, to which the cam discs are attached, but, instead a continuous core region through which each cam segment of the shaft or each segment of the shaft runs.” Figures 13 through 16 illustrate embodiments of shafts with and without a continuous core region as viewed along a central axis. In Figure 13, shown below, “a continuous core region 22 is provided” (p. 22, line 22), whereas in Figure 14, also shown below, “a core region of about zero is provided” (p. 23, lines 5-6). Thus, Figure 13 illustrates an embodiment of a shaft with a continuous core region and Figure 14 illustrates an embodiment without a continuous core region.

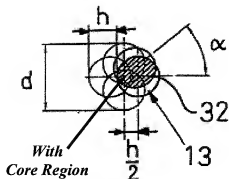


Figure 13

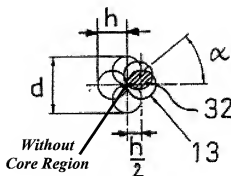


Figure 14

In response to the Examiner's statement that "[i]t is not clear whether applicant's shaft has a core shaft or does not have a core shaft," Applicant first notes that a "shaft comprising a single piece of homogenous material" as recited in Claim 1 does not have a core **shaft**. However, such a shaft can have a continuous core **region**. Applicant notes that amended Claim 1 recites "the shaft is *without a continuous core region*." The cam segments of such a shaft can meet at a central access (see, e.g., Figure 14) or form a core orifice at the central axis (see, e.g., Figures 15 and 16). In contrast, new Claim 21 recites "the shaft *has a continuous core region* having a diameter less than 3 mm." See, e.g., Figure 13. New Claim 35 does not recite a continuous core region, thus can include shafts with or without a continuous core region. Claim 35 recites that the "ratio of the outside diameter to the stroke is less than 4:1." The embodiments described with respect to Figures 13-16 contain this feature.

When a core shaft is used, as in the prior art, it is generally stable enough to provide a rigid support surface for supporting cam discs. The cams are pushed onto the core shaft and fixed there by means of the shape of the provided core shaft, e.g. as a hexagonal surface. In contrast, the continuous core region of the present invention is not a core shaft, as embodiments of the present invention are provided as a "one-piece shaft comprising a single homogenous piece of material" wherein "the shaft [has] integral cam segments offset with respect to one another."

When looking in the direction of a central axis (numbered 21 in Figure 2), the area or region all cam segments are going through is denoted the "continuous core region" (numbered 22 in Figures 2B-2E). In certain embodiments, such as those illustrated in Figures 14-16, there is *no* continuous core region. With such a shaft, a very high lamella stroke is possible as compared to the prior art shafts having a core shaft and cams mounted thereon.

The small continuous core region of certain embodiments can measure about 2-3 mm and the shaft of certain embodiments can have a length of about 3 cm and a diameter of about 1 cm as measured between the outermost points of the cam segments offset one to another. Such a small shaft can withstand enormous mechanical forces during its use in a pumping apparatus with a peristaltic drive device for pumping a medium through a hose. In contrast, Applicant respectfully submits that it would not be possible to provide a very small *core shaft* having a diameter of 2-3 mm and cams or cam segments mounted thereon that can withstand such enormous mechanical forces, as such a small *core shaft* having a diameter of 2-3 mm is not stable enough to withstand these forces. Further, such a shaft having a *core shaft* does not provide a large supporting surface to be able to fix cams or cam segments thereon. Any cams or cam segments fixed on such a small core shaft will not maintain their position on the supporting surface of the core shaft, but rather will move about the shaft, which will lead to problems during the operation of the pumping apparatus.

Camshaft as used in automobiles and other internal combustion engines are very large as compared to the embodiments of the present invention for use in a medical apparatus. It would not be possible to shrink an automobile camshaft since such a shaft would not be able to withstand the mechanical forces acting on the shaft during use in a pumping apparatus for medical use. In particular, the shaft would be unable to withstand the shearing forces during use. Further, such camshafts generally have a large *continuous core region* such that the lamella stroke provided by the shafts is decidedly lower as compared to the lamella stroke provided with the shaft in embodiments of the present invention not having a *continuous core region*, such as recited in Claim 1, or a *continuous core region* having the characteristics specified such as recited in Claims 21 or 35.

Rejection under §35 U.S.C. §103(a) over Magnus in view of Itabashi or Nakamura or Smith

The Examiner rejected Claims 1, 3-9, 11-13, and 15-18 under 35 U.S.C. § 103(a) as being unpatentable over Magnus (USPN 5,558,507) in view of Itabashi et al (USPN 5,676,192) or Nakamura et al (USPN 5,778,530) or Smith et al (USPN 6,289,764). Claims 1-2 and 5-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Magnus in view of Itabashi or Nakamura or Smith, in further view of Goi (USPN 5,263,830). Claim 14 was rejected under 35

U.S.C. § 103(a) as being unpatentable over Magnus in view of Itabashi, Nakamura or Smith, in further view of Romanelli et al (USPN 4,755,168).

Applicant respectfully submits that, as stated in the M.P.E.P. at § 2143, "The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR v. Teleflex*, 550 U.S. at 398, 82 USPQ2d at 1395. Applicant further submits that the cited references fail to describe at least one feature of each of Claims 1, 3-9, 11-13, and 15-18.

Claim 1 is directed to a pumping apparatus that includes, for example, "a one-piece shaft comprising a single homogenous piece of material with integral cams." Claim 1 also recites "the shaft is without a continuous core region." Independent Claims 5, 11, and 16-18 recite substantially similar features. Applicant submits that the applied art fails to teach or suggest the above features.

As mentioned above, the "continuous core region" is described in the specification as the "region through which each cam segment of the shaft or each segment of the shaft runs." Figure 13 illustrates an embodiment of a shaft in which a core region is provided, whereas Figure 14 illustrates an embodiment of a shaft without a core region. Figures 15 and 16 each illustrates another embodiment of a shaft without a core region in which the cam segments "rotate about [an] orifice." See p. 22, lines 23-24.

Applicant submits that none of the applied art references disclose a shaft without a continuous core region. Magnus generally discloses a shaft "made up of stub shafts (8) which project on one size (a) of an eccentric disk (7) and engage in corresponding recesses (9) in the adjacent eccentric disk (7)." See Magnus at c. 1, ll. 37-41. Magnus discloses that the "helically protruding eccentric disks 7 rotate about a common axis x—x. This axis extends vertically, as does the course of the hose. The common axis x—x results from a coaxial addition of sub shafts 8 in the vertical direction" (emphasis added). See Magnus at c. 4, ll. 34-38. Thus, Magnus fails to disclose a shaft without a continuous core region.

Likewise, Itabashi, Nakamura, Smith, Goi, and Romanelli fail to disclose a shaft without a continuous core region. Itabashi discloses a "cam shaft body 6 including ... a plurality of shaft

portions 3.” See Itabashi at c. 2, ll. 18-19. Nakamura discloses a camshaft manufacturing method to produce a camshaft 1 having cam lobes 2. See Nakamura at Figure 1 and c. 1, ll. 44-46. Smith discloses “a camshaft shaft comprising a central shaft, having concentric journal bearings and eccentric cams.” See Smith at c. 2, ll. 2-3. Goi discloses “a peristaltic pump assembly” including a “drive shaft 13.” See Goi at c. 4, ll. 31-35. Romanelli discloses a “reversible peristaltic pump” but fails to teach or suggest any characteristics regarding a shaft. Thus, none of the applied art references teaches or suggests a shaft without a continuous core region.

Each of independent Claims 1, 5, 11, and 16-18 recite “the shaft is without a continuous core region.” Applicant respectfully submits that the applied art fails to teach, at least, this feature. Thus, Applicant respectfully submits Claims 1, 5, 11, and 16-18 contain patentable subject matter and are allowable for at least this reason.

Claims 3-4, 6-10, 12-15, and 19-20 depend, either directly or indirectly, from one of the above-discussed independent claims. In view of the patentability of their respective base claims and the additional features recited therein, Applicant respectfully submits that the dependent claims are likewise in condition for allowance. Therefore, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. 103(a).

Claim 20, as amended, recites “the cam segments define a core orifice.” Although Claim 20 is allowed at least for the reasons set forth above, Applicant respectfully submits that none of the applied art illustrates a shaft having a core orifice. Figures 15 and 16, shown below, illustrates an embodiment of a shaft having a core orifice.

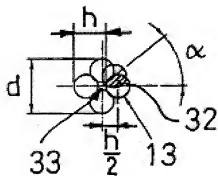


Figure 15

With Core Orifice (33)

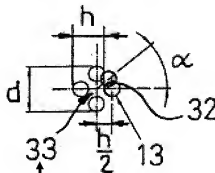


Figure 16

With Core Orifice (33)

The originally filed specification, at page 22, lines 18-24, states, "the cam segments not only do not overlap or meet one another in a middle region, that is to say in the region of an imaginary center line 21, in the projection of the shaft into the plane, but on the contrary, form an orifice 33 there." Applicant respectfully submits that none of the applied art discloses a shaft wherein "cam segments define a core orifice" as recited in Claim 20. Thus, in addition for the reasons set for above, Applicant submits that Claim 20 is in condition for allowance.

#### Discussion of New Claims

Applicant has added Claims 21-35. Claim 21 is directed to a pumping apparatus that includes, for example, "a one-piece shaft comprising a single homogenous piece of material with integral cams." Claim 21 further recites "the shaft has a continuous core region having a diameter less than 3 mm." Independent Claims 25 and 30 recite substantially similar features. Now-cancelled Claim 2 contained a similar feature, reciting "a continuous core region having a diameter between 3 mm and about zero." Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Magnus in view of Itabashi or Nakamura or Smith in further view of Goi. In order to expedite prosecution, Applicant respectfully presents remarks regarding this feature and respectfully submits that the applied art fails to teach or suggest "a continuous core region having a diameter less than 3 mm."

The Examiner stated "Goi does lack the specific size of the continuous core region. It would have been obvious to one having ordinary skill in the art at the time the invention was made [to make] the continuous core region between 3 mm an almost zero, since the claimed values are merely an optimum or workable range. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233." (emphasis added).

Applicant respectfully submits that a *prima facie* case of obviousness with respect to ranges only applies "where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art.'" See M.P.E.P. § 2144.05.I. Applicant further submits that the claimed range of "less than 3 mm" does not "overlap or lie inside ranges disclosed by the art." In fact, the applied art does not disclose any range regarding the diameter of the continuous core region. Thus, Applicant

respectfully submits that a *prima facie* case of obviousness with respect to Claims 21-37 cannot be established on the basis of these references.

Applicant further submits that, as stated in the M.P.E.P. at § 2144.05.II.B, “[a] particular parameter must first be recognized as a results-effective variable, i.e. a variable which achieved a recognized result, before the determination of the optimum or workable ranges of said variable might be considered as routine experimentation. *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).” In response to the above, the Examiner stated “this is a results-effective variable.”

Applicant respectfully submits that the appropriate inquiry is not whether or not a particular variable is a results-effective variable, but rather whether it was recognized in the prior art as being a result-effective variable. As noted above, the applied art does not disclose any range or other information regarding the diameter of the continuous core region. Thus, Applicant respectfully submits that a *prima facie* case of obviousness with respect to Claims 21-34 cannot be established on the basis of these references.

Claim 35 is directed to a pumping apparatus that includes, for example, “a one-piece shaft comprising a single homogenous piece of material with integral cams.” Claim 35 recites “the ratio of outside diameter to the stroke is less than 4:1.” Claim 19 contains a similar feature, reciting “the ratio between the lamella height (c) and the lamella stroke (h) is from about 4:1 to 1:1.” Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Magnus in view of Itabashi or Nakamura or Smith. In order to expedite prosecution, Applicant respectfully presents remarks regarding this feature and respectfully submits that the applied art fails to teach or suggest such a ratio of less than 4:1.

Page 21, lines 34-35, of the originally filed specification describes an “outside diameter  $d$  around which the rotating cam segments run.” The specification further states that the “outside diameter  $d$  corresponds approximately to a lamella height or the inside diameter of the passage orifice 15 through a lamella.” Figures 13-16 illustrate the outside diameter  $d$ .

Page 20, lines 7-9, of the originally filed specification state that “the stroke  $h$  can be determined, that is to say the dimension by which the lamellae are moved to and fro at a maximum.” With respect to the shaft, the stroke can be envisioned as the distance between the

outer edge of a cam segment to the inner edge of the opposite cam segment. Figures 13-16 also illustrate the stroke *h*.

With respect to Claim 19, the Examiner stated that "Magnus does not fully disclose the ratio. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to reach such a ratio, since the claimed values are merely an optimum or workable range. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only ordinary skill in the art. *In re Aller*, 105 USPQ 233" (emphasis added).

Applicant respectfully submits that a *prima facie* case of obviousness with respect to ranges only applies "where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art.'" See M.P.E.P. § 2144.05.I. Applicant further submits that the claimed range of "less than 4:1" does not "overlap or lie inside ranges disclosed by the art." In fact, the applied art does not disclose any specific ratio regarding the outside diameter to the stroke. Thus, Applicant respectfully submits that a *prima facie* case of obviousness with respect to Claim 35 cannot be established on the basis of these references.

### **CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims, and that those claims are in condition for allowance. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other



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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Although Applicant has presented remarks about certain dependent claims, Applicant does not necessarily agree with the characterization of the remaining dependent claims or the prior art as applied to those claims. Further, although Applicant has not presented remarks regarding the combination of the applied references, Applicant is not conceding that the combination is proper. *See, e.g.,* Amendment dated March 16, 2009.


The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain of if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly. In particular, the Examiner is respectfully invited to call Applicant's attorney to resolve any confusion regarding the difference between a *core shaft* and a *continuous core region* or in the specification's description of *outside diameter* and *stroke*.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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